Section 5

DEC 5 2012

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4349 (801) 253-6967 Stephanie Erskine 1721504
	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Ireland Ltd. Parkmore Business Park, Galway, Ireland (353) 91 703 761 (353) 91 771 888 Mark Mullaney 23-Nov-2012 9616662
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit ONE Snare™ System Percutaneous retrieval device device, Percutaneous retrieval
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	AMPLATZ GOOSE NECK SNARE KIT/ CATHETER catheter, embolectomy K972511 ev3 Inc.
Classification	Class II 21 CFR § 870.5150 Division of Cardiovascular Devices	
Intended Use	The ONE Snare™ endovascular snare system is intended for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.	

Device Description	ONE Snare™ System contains: (1) Snare, (1) Snare Catheter, (1) Introducer and (1) Torque Device. The snare is constructed of nitinol cable and a gold plated tungsten loop. The pre-formed snare loop can be introduced through catheters without risk of snare deformation because of the snare's super-elastic construction. The snare catheter is constructed of polyether block amide (Pebax®) and contains a platinum/iridium radiopaque marker band.
Technological Characteristics	Technological characteristics of the subject Merit ONE Snare™ system are substantially equivalent to those of the predicate, the currently marketed AMPLATZ GOOSE NECK SNARE KIT/ CATHETER, manufactured by ev3 Inc., 510(k) K972511.
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests performed on the Merit ONE Snare™ system were designed to demonstrate that the device meets critical design specifications as well as clinical performance attributes for its intended use. Where appropriate, the tests were based on the requirements of the following documents: • FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995. • ISO 11070: 1998, Sterile Single-Use Intravascular Catheter Introducers. • ISO 10555-1 1995 Sterile, single-use intravascular catheters, Part 1 – General Requirements. • ISO 594-1:1996, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements • ISO 594-2:1998, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings • ASTM F 2096-11; Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) • ASTM F 1929-98 (Reapproved 2004); Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration • ASTM F 88-09; Standard Test Method for Seal Strength of Flexible Barrier Materials. • ASTM D4169 – 09 Standard Practice for Performance Testing of Shipping Containers and Systems • ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ISO 11135:2007 – *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-1: 2009, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing within a risk management process,* and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.

The Merit ONE Snare™ system was compared to the predicate device for various performance attributes that demonstrate substantial equivalence. The following is a list of all significant testing that was successfully completed:

Safety & Performance Tests (continued)

ONE Snare System (Snare device, Catheter, Introducer and Torque Device)

- Surface Finish, Torque Strength, Torqueability, Compatibility of snare with snare catheter, Snare Catheter to Guiding Catheter compatibility, Snare introducer fit, Introducer Removal Force from Snare and Dimensional Inspection

Snare

- Radiodetectability (Snare wire), Size Designation, Tensile Test, Tip Flexibility, Fracture Test & Flexing Test and Corrosion resistance

Catheter & Introducer

- Radiodetectability (Snare catheter / marker bands), Catheter Atraumatic Tip Finish, Marker Band Retention, Force at break (at Catheter Tip and Junction between Catheter Hub and Tube), Catheter Pushability (kink or accordion resistance) & Catheter flexibility (buckling resistance), Hub with Female Luer testing, Dimensions, Freedom from leakage, Surface Finish, Force at break (Junction between Introducer Hub and Tube), Corrosion resistance and Snare Torque Strength.

Biocompatibility testing included

- L929 MEM Elution: MEM extraction
- Kligman Maximization: Saline and cottonseed oil extractions
- Irritation – Intracutaneous Injection Test – Intracutaneous Injection: Saline and cottonseed oil extractions
- Systemic Injection: Saline and cottonseed oil extractions
- Material Medicated Rabbit Pyrogen Test: Saline extraction
- Genotoxicity - Salonella typhimurium and Escherichia Coli Reverse Mutation Assay – ISO
- Hemocompatibility – Rabbit Blood – Indirect
- Hemocompatibility – Rabbit Blood – direct
- Hemocompatibility – Complement Activation Assay – ISO direct Contact
- Hemocompatibility – In Vivo Thrombogenicity study in Dogs
- USP Physicochemical Tests for Plastics USP <661> Non-Volatile Residue

Safety & Performance Tests (continued)	Packaging performance before and after exposure to accelerated aging and simulated shipping and handling conditions • bubble emission • dye penetration • seal peel tensile strength • burst strength • visual inspection
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject Merit ONE Snare™ system meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the currently marketed AMPLATZ GOOSE NECK SNARE KIT/ CATHETER, manufactured by ev3 Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 5 2012

Merit Medical Systems, Inc.
Mr. Mark Mullaney
Regulatory Affairs Manager
1600 West Merit Parkway
South Jordan, UT 4095

Re: K122088
Trade/Device Name: Merit ONE Snare System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: November 22, 2012
Received: November 26, 2012

Dear Mr. Mullaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K122088

Device Name: Merit ONE Snare™ System

Indications for Use:

The ONE Snare™ endovascular snare system is intended for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects.

Retrieval and manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122088